IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIC A/S and ANTON MAYR, Plaintiffs, v. ACAMBIS INC. and ACAMBIS PLC, Defendants.	)	C.A. No. 05-614 (SLR) **REDACTED PUBLIC VERSION**

REPLY BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS, OR IN THE ALTERNATIVE FOR SUMMARY JUDGMENT, ON ALL CLAIMS

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INTRODUCTION

Defendants Acambis Inc. and Acambis plc ("Acambis") hereby reply to plaintiff Bavarian Nordic's ("BN") answering brief in opposition to defendants' motion to dismiss, or in the alternative for summary judgment, on all claims. (Plaintiff Mayr is not listed on the opposing brief and did not file a separate opposition.) BN's opposing brief does nothing to salvage plaintiffs' case.

Prior to its opposition brief, BN asserted that the converted property was the "right to commercialize" a virus. That intangible right is not recognized in conversion. BN's opposition now argues that the conversion claim is not based on a "mere 'right to commercialize,'" but also involves the physical virus. *See* D.I. 125, Pl. Opposition Br. at 18. Plaintiffs' allegations and the undisputed facts make clear that the claim can involve nothing more than the right to commercial use, which is not actionable in conversion. BN's brief also seeks to avoid the undisputed fact that Acambis did not exclude plaintiffs from *any* property at *any* time (but only received a copy of a sample of a self-replicating viral strain). Contrary to BN's legal argument, *exclusion* from the subject property by the defendant is a fundamental prerequisite to *any* conversion claim, whether based on tangible or intangible property.

BN's opposition also confirms that plaintiffs' unfair competition claims must be rejected. Plaintiffs cannot deny that Acambis' vaccine product, MVA3000, is a proprietary vaccine (and not simply a viral strain) developed by Acambis and its manufacturing partner, Baxter. Nor can it demonstrate any literally false statements made by Acambis in connection with the provision of the vaccine to the U.S. Government, the sole consumer in the marketplace, or any possible confusion by the U.S. Government as to the origin of the vaccine or its underlying strain. Indeed, the U.S. Government provided the underlying strain to Acambis following the Government's investigation and rejection of BN's claims.

As a result, whether pursuant to Rule 12(c) or 56, judgment on plaintiffs' claims should be entered in favor of defendants.

ARGUMENT

I. PLAINTIFFS' CONVERSION CLAIM MUST BE REJECTED

A. Intangible Right to Commercial Use at Issue

BN does not challenge the rule that intangible rights are not actionable in conversion in either Maryland or Massachusetts.[1] *See* D.I. 112, Def. Opening Br. at 20-22. Nor does it challenge the rule that the right to commercialize is an intangible right that *no precedent* has recognized as actionable in conversion. *See id.* at 22-23. Rather, it argues that its claim is "not limited to any mere 'right to commercialize' the strain," but also involves the tangible copy of the MVA 572 strain provided to Acambis by NIH. D.I. 125, Pl. Opposition Br. at 18; *see also id.* at 3 ("[T]he act of conversion simply relates to the receipt by Dr. Moss of tangible vials of specific vaccinia virus, MVA 572, from Prof. Mayr, and Acambis' receipt of the progeny of that virus.").

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[1] Defendants argue in their opening brief that either Maryland or Massachusetts law should apply to plaintiffs' conversion claim. *See* D.I. 112, Def. Opening Br. at 18-20. (Defendants also explain that Maryland and/or Massachusetts may look elsewhere for the applicable law on certain issues, such as ownership. *Id.* at 20 n.9.) In plaintiffs' motion for summary judgment, they argue that Massachusetts law "most properly applies" to the conversion claim. D.I. 115, Pl. Opening Br. at 18. While there do not appear to be any differences in Maryland or Massachusetts law on the relevant issues (and plaintiffs do not point to any), given the assertions regarding NIH in plaintiffs' summary judgment briefing – including that plaintiffs' conversion claim is based on an alleged breach of contract by NIH, and that Acambis merely received "progeny" of the virus provided by Mayr to NIH (while NIH retains the original sample) – it appears that Maryland law may more appropriately apply. Indeed, plaintiffs have consistently argued that the conversion "started" with NIH's receipt of the strain in its laboratories in Maryland. *See* D.I. 107, 10/5/06 Discovery Conference Tr. at 6; D.I. 125, Pl. Opposition Br. at 3.

The mere "receipt" of MVA 572 or its "progeny" cannot be actionable in conversion – that material is undisputedly available to *anyone*. *See* D.I. 112, Def. Opening Br. at 22 n.10. For instance, as noted in plaintiffs' complaint, the same MVA 572 provided to NIH was available through the ECACC depository to *anyone* seeking a copy of the strain. D.I. 85, First Amended Compl. ¶¶ 25-26; *see also* ECACC website Order Form, *available at* http://www.ecacc.org.uk/ (last visited Nov. 6, 2006); Ex. 52 to Def. Opening Br., Straus Supplemental Expert Report at ¶10. Similarly, as acknowledged in plaintiff's opposing brief, Prof. Mayr's reference to the strain in published articles "require[s]" that he "make samples" of the material "available to other scientists for research." D.I. 125, Pl. Opposition Br. at 9. It is also undisputed that Mayr willingly provided the MVA 572 sample in this case to NIH without any understanding that the sample would be returned. *See* Ex. 27 to Def. Opening Br., 9/12/01 Mayr letter to Moss (Mayr 9/21/2006 deposition exhibit 14); Ex. 2 to Def. Opening Br., Mayr 9/21/2006 deposition at 55-56.

In fact, Mayr testified in deposition that he took an [redacted] (*see* Ex. 5 to Def. Opening Br., Mayr 12/14/2005 deposition at 41), was [redacted]" (*id.* at 59), and found it [redacted] (Ex.2 to Def. Opening Br., Mayr 9/21/2006 deposition at 52). *See also* Ex. 13 to Def. Opening Br., June 1995 Mayr letter at BNITC00091849 (boasting that MVA 572 [redacted]. As BN CEO Peter Wulff acknowledged, [redacted] Ex. 18 to Def. Opening Br., 11/10/2004 Wulff email at

BNITC00319145-46; *see also* Ex. 23 to Def. Opening Br., 9/8/1999 Wulff email at BNITC00027436 (cataloguing Mayr's distributions). Further, as plaintiffs' purported expert Straus testified, Prof. Mayr's wide dissemination was not limited to research institutions, but also included routine distributions to *companies*. Ex. 7 to Def. Opening Br., Straus 11/30/06 deposition at 53-56.[2]

Rather than the viral strain, this case has always been about the purported right to commercial use of the strain – *i.e.*, the right to make money from the strain. *See Miles, Inc. v. Scripps Clinic & Research Found.*, 810 F. Supp. 1091, 1095 (S.D. Cal. 1993) ("[T]he interest at stake here [is] making money from the commercialization of a cell line").[3] As BN has clearly stated:

> In this action, Bavarian Nordic *predicates* its "property interest in MVA-572 and its progeny" not on any patent it owns, *but on "its*

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[2] BN acknowledges that Mayr's prior distributions were made without any written restriction, but claims that the recipients were subject to an "implied" restriction to use the strain for research purposes only. As explained in Acambis' opposition to plaintiffs' motion for summary judgment, there is no credible support for that claim. *See* D.I. 122, Def. Opposition Br. at 15-23. Further, as explained in Acambis' opening brief, on at least one occasion, Mayr provided MVA 572 to another entity [redacted]) *knowing* that it would be used for commercial purposes. D.I. 112, Def. Opening Br. at 8, ¶ 10 and n. 7. BN disingenuously argues in its opposition brief that such distribution was "for research purposes only" D.I. 125, Pl. Opposition Br. at 10. According to the clear testimony of BN CEO Peter Wulff, Prof. Mayr [redacted] Ex. 20 to Def. Opening Br., Wulff 9/21/06 deposition at 186-87.

[3] While the plaintiffs in the *Miles* case initially argued that their conversion claim involved both a physical cell line (tangible property) and the "right to commercialize" that cell line, they "later conceded," as plaintiffs should here, that the property at issue was limited to the intangible "right to commercialize." *Miles*, 810 F. Supp. at 1093 n.3.

> *exclusive license from Professor Mayr for the commercialization of all MVA strains.*"

D.I. 16, BN's Reply in Support of Motion to Strike (10/18/05) at 2 (emphasis added), *citing* Complaint at ¶ 46; *see also* D.I. 38, BN's Motion to Amend (5/22/06) at 2 ("Bavarian Nordic bases its *right to commercialize* MVA in [its] agreements with Prof. Mayr.") (emphasis added).

According to plaintiffs' own repeated assertions, the right to commercial use is separable from the physical strain and may only be obtained via a license, which by definition represents *intangible* property. *See* D.I. 115, Pl. Opening Br. at 25 ("Absent an explicit license to commercialize the strain – a license only Bavarian Nordic possesses – use of MVA 572 is authorized for research purposes only."); D.I. 125, Pl. Opposition Br. at 5 ("BN had exclusive license to commercially use Prof. Mayr's proprietary MVA material."); *id.* at 10; *see also* Ex. 46 to Def. Opening Br., March 2004 Supplemental Agreement (BNITC00017193) at ¶ 2.1 (BN-Mayr contract purportedly granting BN the [redacted] of MVA strains); Ex. H to Pl. Opening Br., Einhorn Report at ¶ 6(a); Ex. I to Pl. Opening Br., Drillien Report at ¶ 14; *see also IDAS Res. N.V. v. Empressa Nacional de Diamantes*, 2006 U.S. Dist. LEXIS 77928 at *12 (D.D.C. Oct. 26, 2006) ("licenses are regularly treated as intangible property."), citing, *inter alia*, *Members of Peanut Quota Holders Ass'n, Inc. v. United States*, 412 F.3d 1323, 1330 (Fed. Cir. 2005) ("government issued [grazing and fishing] permits and licenses" are "intangible property").

However, as explained in defendants' opening brief (and not disputed by BN), an intangible right may only be protected if "merged" into a transferable document. *See* D.I. 112, Def. Opening Br. at 20-23. In this case, BN makes no attempt to argue that the right to commercial use was "merged" into a license at the time the sample strain was provided to NIH

and a copy subsequently sent to Acambis.[4] *See* D.I. 112, Def. Opening Br. at 20-21; *see also Propper Demonstration Sales of Ohio, Inc. v. F. W. Woolworth Co.*, 1990 U.S. Dist. LEXIS 20896 at *10-11 (D. Ohio Nov. 29, 1990) (conversion claim based on expired lease could not succeed because, "[a]lthough a lease represents an intangible right to possess and use land, an expired lease represents no such right.").

BN also argues that defendants "confuse" plaintiffs' conversion claim for an intellectual property claim.[5] D.I. 125, Pl. Opposition Br. at 3. But *BN* is confused. For instance, BN argues that intangible property is synonymous with and limited to intellectual property. *See id.* at 3 ("It is well established that intellectual property, or intangible rights, refers to patents, trademarks, copyright and trade secrets."). While intangible property rights encompass intellectual property rights, they also include many other rights embodied by written documents. *See, e.g,* BLACK'S LAW DICTIONARY 558 (6th ed. 1991) (defining "intangible property" as "such property as has no intrinsic or marketable value, but is merely the representative or evidence of

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[4] Nor could it given the following undisputed facts: (1) there was no contract in place at the time that the strain was provided to NIH (and subsequently to Acambis); (2) even if the contract then under negotiation had been in place, like all prior contracts between BN and Mayr, it would merely have provided BN with "access" (not ownership) rights; (3) the November 2002 contract that plaintiffs claim transferred "ownership" from Mayr to BN was not executed until after the strain was provided to NIH in September 2001 (and the copy subsequently provided by NIH to Acambis in September 2002); and (4) the November 2002 contract was limited to strains in Mayr's "possession," which undisputedly would not include the strain previously provided to NIH or the subsequent copy provided to Acambis. *See* D.I. 112, Def. Opening Br. at 13-14, 26-27; D.I. 125, Pl. Opposition Br. at 5.

[5] In connection with this argument, BN references the parallel ITC proceeding and states that the ITC ALJ's initial determination "included a finding that Acambis' product infringed BN's patents." D.I. 125, Pl. Opposition Br. at 2. Plaintiffs fail to mention that the initial determination also found *every* asserted patent claim *invalid* on multiple bases. *See* Ex. 58, Initial Determination at 101-02 ("all of [the '893 asserted] claims are invalid as obvious" and all of the '752 asserted claims "are invalid for lack of enablement, lack of written description" and inventorship.).

value, such as certificates of stock, bonds, promissory notes, copyrights, and franchises."). BN also inexplicably cites to Federal Circuit law for the summary judgment standard at issue in this case. *See* D.I. 125, Pl. Opposition Br. at 15.

BN further argues that Acambis is trying to "shoehorn" plaintiffs' claim into a "right to commercialize" case. But Acambis did not conceive that language – BN itself claims that it "bases its *right to commercialize* MVA" on its agreements with Mayr. D.I. 38, BN's Motion to Amend at 2 (emphasis added). And BN's own expert Jarosz clearly opined in his report – a report submitted by BN's counsel – that the property at issue is the "right to commercialize." *See* Ex. Q to Pl. Opening Br., Jarosz report at 5-6. Plaintiffs' other experts similarly acknowledge that the case involves the purported intangible right to commercial use. *See* Ex. 59, Drillien 11/24/06 deposition at 37-38 [redacted]. BN now argues that purported expert Jarosz's statement "occurs strictly within the context of evaluating the damages which BN has suffered...." *See* D.I. 125, Pl. Opposition Br. at 19 (conceding that expert opinion "admittedly references a 'right to commercialize'"). Even if accepted as true, plaintiffs' damages claim *must* be dismissed as based on an *admittedly* intangible right.[6]

If anything, BN is seeking to shoehorn a mere breach of contract claim against NIH into a conversion claim against a competitor, Acambis. BN simply wants to avoid litigation

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[6] Further, the 505,000 doses of vaccine about which BN complains are undisputedly the property of the U.S. Government procured for the purpose of protecting the American people against a terrorist attack. *See* D.I. 125, Pl. Opposition Br. at 22 (acknowledging that doses have been "sold" to the U.S. Government). That U.S. Government property cannot be recovered in a suit against Acambis to which the U.S. Government is not party. *See Acierno v. Preit-Rubin, Inc.*, 199 F.R.D. 157, 162-63 (D. Del. 2001) (dismissing claim pursuant to Rule 19 for failure to join necessary government entity).

against its largest customer, NIH. *See* Ex. 20 to Def. Opening Br., 9/21/06 Wulff deposition at 120 (quoted in Def. Opening Br. at p. 25, n. 13). BN's rant about NIH's opposition to BN's subpoena only confirms that NIH was in jeopardy of being sued by plaintiffs.[7] *See* D.I. 125, Pl. Opposition Br. at 1-2. As a matter of law, a conversion claim may not be predicated on a mere breach of contract. *See* D.I. 112, Def. Opening Br. at 25-26.

In the end, there is no escaping the fact that plaintiffs' claim involves an intangible right that is simply not actionable in conversion.

B. Defendants Have Not Excluded Plaintiffs from Any Property

In addition, whether based on the intangible right to commercial use or the tangible physical strain, judgment must be granted for defendants on plaintiffs' conversion claim

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[7] Given BN's deliberate decision not to sue NIH, it cannot be heard to complain that NIH "refused" to participate in discovery in this case. Nor can plaintiffs complain regarding Dr. Moss' participation in this case. Plaintiffs misleadingly state that Dr. Moss "has refused to provide testimony" when, in fact, Dr. Moss cooperated and provided full and complete testimony *in his personal capacity* on August 28, 2006 in response to a subpoena from BN. D.I. 125, Pl. Opposition Br. at 2; *see also* Ex. 42 to Def. Opposition Br., Moss deposition. That testimony debunked plaintiffs' false allegations of conflict of interest, establishing that Dr. Moss had at all times adhered to NIH procedures and had openly sought and obtained approval for his prior consulting activities for Acambis' predecessor, OraVax, which were terminated before the events in question. *See* D.I. 122, Def. Opposition Br. at 21 n.17. Separately, plaintiffs sought to compel the NIH to provide Dr. Moss for testimony in regard to his work at NIH. Defendants also sought testimony from the NIH, following the correct *Touhy* procedures, as defendants are confident that the testimony would fully support their position. The NIH responded that the NIH had acted properly with regard to the transactions in question, but objected to the subpoena noting that plaintiffs had not complied with the requirements of 45 C.F.R. Part 2 (2006). Ex. 60, 8/1/2006 Dr. Kington letter. While "[a]ssuming all of the representations of Bavarian Nordic are true," Magistrate Judge Day agreed with NIH, finding strong Fourth Circuit law favoring NIH's position. Ex. A to Pl. Opposition Br. at 51. Those facts would hardly support a negative inference against *Acambis*, as plaintiffs argue without any legal citation. *See* D.I. 125, Pl. Opposition Br. at 2.

for the wholly independent reason that Acambis has never excluded plaintiffs from *any* property. *See* D.I. 112, Def. Opening Br. at 27-30.

In fact, BN admits (as it must) that Acambis *never* received or possessed the sample strain provided to NIH, but merely received a clone ("progeny") of that strain from one of the batches of copies made by NIH. *See* D.I. 125, Pl. Opposition Br. at 3. Further, BN does not (and cannot) dispute that it "retains additional vials of MVA 572," a replicable virus, and has the ability to do whatever it wants with those virus stocks. *See id.* at 21. In this respect, BN's analogy to loaning one of "three SAAB cars" is misplaced. *See id.* at 22. This case does not involve a finite res – rather, as BN acknowledges, MVA is a self-replicating virus that can be reproduced by the "million." *See id.* at 3 ("[T]he viral products contained in the vial can replicate and produce millions of doses of valuable small pox vaccine."). In other words, plaintiffs can have as much MVA 572 as they want simply by growing up more of the virus. Indeed, plaintiffs concede that NIH has made copies of the virus provided by Mayr, and NIH has given copies to several other entities aside from Acambis.[8] *See* D.I. 112, Def. Opening Br. at 13 n.8.

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[8] While asserting conversion against the MVA 572 "progeny" derived by NIH, plaintiff BN has represented that MVA F6 is free from any conversion claim despite also being derived from MVA 572. *See* D.I. 122, Def. Opposition Br. at 13-14. BN now attaches Gerd Sutter's entire 1989 thesis and its English translation – a 135-page exhibit – to support of the claim that Sutter's MVA F6 virus was derived from MVA 574, not MVA 572. *See* D.I. 125, Pl. Opposition Br. at 10 & Exhibit H to Pl. Opposition Br. However, as BN CEO Wulff has repeatedly testified (including testimony attached to BN's opposition), Sutter in fact started with *MVA 572*. *See* Exhibit J to Pl. Opposition at 164; Ex. 61, ITC Hearing Tr. 132-133 (Wulff) [redacted]

(continued . . .)

Rather than challenge the facts, BN argues that the case law requiring that a defendant convert the subject property to the "exclusion" of the plaintiff applies only to "intangible property." *See* D.I. 125, Pl. Opposition Br. at 22. That argument has no merit. First, as discussed above, this case involves the *intangible* right to commercial use of a viral strain. Second, the case law regarding the exclusion element of conversion is not limited to intangible property. *See, e.g., Pearson v. Dodd*, 410 F.2d 701, 707 (D.C. Cir. 1969) ("It is clear that on the agreed facts appellants committed no conversion of the *physical documents* taken from appellee's files. Those documents were removed from the files at night, photocopied, and returned to the files undamaged before office operations resumed in the morning.") (emphasis added). Rather, the common thread through the cases involving the alleged conversion of *copies* is that, like this case, they involve the alleged conversion of property that is *replicable*.

For instance, in *Orteck International Inc. v. Transpacific Tire & Wheel, Inc.,* the property at issue was a copy of a customer list. No. DKC 2005-2883, 2006 U.S. Dist. LEXIS 67702 (D. Md. Sept. 5, 2006). While the court found that information contained in the customer list was intangible property that could not support a conversion claim, it did not rely on that basis alone for dismissing plaintiff's claim. Rather, the court held that, even assuming it were the type of property that would support a conversion claim, the claim would still fail for the independent reason that plaintiff could not show that defendant's use of a *copy* of the customer list was "to the complete exclusion" of the plaintiff. *Id.* at *78 (citing to *Yost v. Early*, 87 Md. App. 364, 589 A.2d 1291 (1991)). Similarly, in *Yost v. Early*, the plaintiff voluntarily provided COBOL

(. . . continued)

[redacted] According to Wulff, Sutter [redacted] Ex. 62, Wulff 2/9/06 deposition at 37-38.

computer coding sheets to Saturn. 87 Md. App. 364 (1991). The original property – the coding sheets – had either been returned or discarded, but copies of the computer program had been made and existed on disk or tape in the possession of defendant. The court rejected plaintiff's conversion claim because it "was not for his original property, but for its copy." *Id.* at 388. The court noted that conversion of a copy "cannot support an action for constructive conversion," but requires the exercise of dominion and control to the "complete exclusion" of the owner.[9] *Id.*; *accord FMC Corp. v. Cap. Cities/ABC, Inc.*, 915 F.2d 300, 304 (7th Cir. 1990) ("Where, as here, the owner does not have the original [documents] and the alleged converter has the originals *or* the only known copies of the originals, the retention of such property – to the exclusion of the owner – constitutes conversion. In such a case the copies become the functional equivalents of the originals.").

Finally, BN's argument that this case is akin to a bailor/bailee relationship is mistaken. First, Acambis undisputedly did not receive any bailment from plaintiffs; Acambis received from NIH a copy of the sample provided to NIH. Second, a bailee is one who *temporarily* holds property of the bailor under an express or implied-in-fact contract to *return* the property upon fulfillment of some agreed upon purpose. *See, e.g., King v. Trustees of Boston Univ.*, 420 Mass. 52, 59 (Mass. 1995) ("A bailment is established by 'delivery of personalty for some particular purpose, or on mere deposit, upon a contract, express or implied, that after the purpose has been fulfilled it shall be redelivered to the person who delivered it, or otherwise dealt with according to his directions, or kept until he reclaims it, as the case may be.' 9 S. Williston, Contracts § 1030 (3d ed. 1967)"). Here, there is no suggestion that NIH was required

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[9] The *Yost* Court further noted that if the claim were for the "reproduction of his coding sheets," it would be preempted by the Federal Copyright Act. 87 Md. App. at 389.

to return the sample to Mayr; rather, it is undisputed that NIH was free to alter, modify, consume and/or destroy the virus. Indeed, plaintiffs have *never* requested the return of the original sample provided to NIH. Clearly, no bailment was contemplated.

II. PLAINTIFFS' UNFAIR COMPETITION CLAIMS MUST BE REJECTED

A. BN's Reverse Passing Off and False Advertising Claims are Barred

BN does not dispute that it does not manufacture or produce the MVA3000 vaccine that the U.S. Government procured from Acambis. This admission alone is fatal to BN's reverse passing off claims pursuant to *Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23 (2003). In *Dastar*, the Supreme Court defined "good" under the Lanham Act as "the tangible product sold in the market place." *Id.* at 31. As BN has alleged, the "vaccine product" Acambis offers is MVA3000. D.I. 85, Amended Complaint at ¶ 20 ("Acambis has partnered with Baxter…to develop a MVA-based smallpox vaccine [and] Baxter manufactures … the MVA-based product MVA3000"); *id.* at ¶ 21 ("While promoting their new vaccine products, Acambis made false and/or misleading statements … regarding Acambis' freedom to operate within the field of MVA-based smallpox vaccines.").

Faced with *Dastar* and its progeny, however, BN attempts to redefine the tangible competing product at issue as a virus, which is but one component of a vaccine, rather than the vaccine itself. But under the Lanham Act, the "tangible product sold in the marketplace" is the end product, *not* any particular *element* that has been incorporated into that product. *See Dastar*, 539 U.S. at 37 ("[W]e conclude that ['origin of goods'] refers to the produce of the tangible goods that are offered for sale"); *Monsanto Co. v. Syngenta Seeds, Inc.*, Civ. No. 04-305, 2006 U.S. Dist. Lexis 54515 (D. Del. Aug. 4, 2006) (Robinson, C.J.) (dismissing plaintiff's unfair trade claims under *Dastar* because the misappropriated technology, a seed trait, was not the

tangible product sold in the marketplace); *see also Gen. Univ. Sys. Inc. v. Lee*, 379 F.3d 131, 149 (5th Cir. 2004) (affirming summary judgment because the plaintiff had not accused the defendant of "taking tangible copies of its software, removing its trademarks, and selling them as its own"); *Schiffer Publ'g, Ltd v. Chronicle Books, LLC*, 350 F. Supp. 2d 613, 618 (E.D. Pa. 2004) ("[B]ecause Defendants are the physical producers – the fabricators, so to speak – of 1000 Patterns, they cannot be held liable under § 43(a)(1)(A) even if they are not the creators of the pictures at issue"); *Bretford Mfg., Inc. v. Smith Sys. Mfg.*, 286 F. Supp. 2d 969, 970-72 (N.D. Ill. 2003), *aff'd* 419 F.3d 576 (7th Cir. 2005) (dismissing reverse passing off claim under *Dastar* where defendant incorporated the plaintiff's table leg into a finished product, *i.e.*, school table, and marketed the table as its own). This is true even if consumers purchase the end product specifically for the particular element at issue. *Monsanto Co.*, 2006 U.S. Dist. Lexis 54515, at *9 ("[T]he seed is the tangible product sold in the marketplace [and t]he court understands that consumers buy the seed for its GA21 trait").

Here, the end product is the MVA3000 vaccine, which is much more than just a virus. Indeed, BN does not point to any evidence to dispute the fact that MVA3000 is manufactured through the complex process – developed by Acambis and Baxter – as described in Acambis' Opening Brief.[10] *See* D.I. 112, Def. Opening Br. at 16 (describing the multi-step manufacturing process). In the ITC proceeding, BN acknowledged the distinction between MVA viruses and the manufactured MVA3000 vaccine, stating that:

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[10] BN erroneously states, without citation, that Baxter used BN's patents as a "roadmap" to manufacturing a vaccine. D.I. 125, Pl. Opposition Br. at 2. In fact, it is impossible that Baxter used BN's patents at all. First, the patents were not published until 2003, at least one year after Acambis submitted a U.S. Government bid. *See* Ex. B to Pl. Opening Br., U.S. Patent No. 6,761,893, U.S. Patent No. 6,913,752. Second, the patents purport to describe how to isolate and identify an MVA derived virus and do not discuss how to manufacture a vaccine. *Id.*

[redacted]

See Ex. 63, BN Statement of Undisputed Material Facts at 5; *see also* Ex. A to Pl. Opening Br., Joint Statement of Facts at 6 [redacted] Because BN does not dispute that Acambis and Baxter manufacture the MVA3000 vaccine, which is the product that is sold to the U.S. Government, BN's reverse passing off claims are barred as a matter of law.

B. Plaintiffs Offer No Evidence of Confusion or Literally False Statements

BN does not dispute that it has no evidence that Acambis caused confusion in the U.S. Government procurement process at the NIH. Rather, BN argues that Acambis (1) confused the FDA in seeking approval for clinical trials of its vaccine and (2) made literally false statements to the government. Both of these claims fail, however, because BN cannot meet its burden of showing that any of Acambis' statements were false or misleading. *See Johnson & Johnson-Merck Consumer Pharma. Co. v. Rhone-Poulenc Rorer Pharma., Inc.*, 19 F.3d 125, 129 (3d Cir. 1994) (stating that the burden is on the plaintiff to "prove that a claim is false or misleading").

First, BN erroneously asserts that the FDA found the name ACAM3000 confusing because it "associates Anton Mayr's MVA … with Acambis' product line." D.I. 125, Pl. Opposition Br. at 30. In fact, the FDA statements cited by BN are not indicative of confusion at

all, much less confusion with Anton Mayr. The FDA's comments do not mention Mayr or BN, and do not indicate that the *FDA* was confused in any way. Rather, the FDA recognized the difference between Acambis' various vaccine products. But it noted that ACAM2000 and ACAM3000 were similar names, and inquired as to how Acambis would ensure that the two Acambis products would not be confused by *clinicians*. *See* Ex. S to Pl. Opposition Br. at AC0092061 ("CBER recognizes the similarity in the names between the ACAM2000 and the ACAM3000 (MVA) vaccine products. How does Acambis plan to assure that these two products are not confused? Is renaming of the products under consideration?"). Subsequently, Acambis changed the name of its vaccine to MVA3000 "in order to eliminate the *possibility* of confusion" by clinicians. *See id.* (emphasis added). There is no other record evidence linking the name MVA3000 to Mayr or BN. Hence, BN cannot prove *actual* deception by Acambis. *See Johnson-Merck*, 19 F.3d at 130 (plaintiff "bears the burden of proving actual deception by a preponderance of the evidence.").

Second, BN argues that it does not need evidence of confusion because it can prove that Acambis made literally false statements to the U.S. Government. *See* D.I. 125, Pl. Opposition Br. at 31 (claiming that BN has "demonstrated several instances in which Acambis made literally false representations to the U.S. Government regarding Acambis' freedom to operate with MVA."). In considering whether a statement is literally false, "a court must determine, first, the unambiguous claim made by the advertisement or product name, and second, whether those claims are false." *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharma. Co.*, 290 F.3d 578, 586 (3d Cir. 2002).

Here, BN cannot identify a single literally false statement, nor does BN cite any affirmative evidence showing that any Acambis statement is literally false. *See* D.I. 125, Pl.

Opposition Br. at 31; *cf. Castrol, Inc. v. Pennzoil Co.*, 987 F.2d 939, 949 (3d Cir. 1993) (finding literal falsity based on plaintiff's "copious affirmative evidence, which included expert testimony, laboratory testing, and field testing"); *Sandoz Pharma Corp. v. Richarson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990) (affirming district court's finding that plaintiff cannot prevail under the Lanham Act because "it has not proved that [defendant's] labeling is false"); *Diamond Triumph Auto Glass, Inc. v. Safelite Glass Corp.*, 441 F. Supp. 2d. 695, 706-07 (M.D. Pa. 2006) (granting summary judgment because plaintiff could not prove that defendant's statements were false). As such, BN has failed to show that there is any disputed issue for trial.

Although BN does not identify any explicit statements, it generally avers that "Acambis made literally false representations to the U.S. Government regarding Acambis' freedom to operate with MVA." D.I. 125, Pl. Opposition Br. at 31. But this is nothing more than a reiteration of BN's reverse passing off claim and, as such, is barred by the *Dastar* precedent. *See Monsanto Co.*, 2006 U.S. Dist. LEXIS 54515, at *12 ("Under Dastar, a false advertising claim that merely rephrases a reverse passing off claim is barred.").

Nevertheless, any "determination of literal falsity rests on an analysis of the message in context." *Rhone-Poulenc*, 19 F.3d at 130. Here, the statements that were made to the NIH concerned Acambis' right to develop the MVA strain.[11] *See* D.I. 125, Pl. Opposition Br. at

[11] Plaintiff's interrogatory responses concerning the basis for its unfair trade claims included only the following three Acambis statements to the U.S. Government. (In its responses BN does not designate any of these statements as literally false):

[redacted]

(continued . . .)

31 (stating that all the statements concern Acambis' freedom to operate). Acambis' understanding of its rights were based on the NIH's representations – Acambis just parroted back to the NIH what the NIH already knew (and had told Acambis). *See, e.g.,* Ex. 64, Higgins 8/25/06 Dep. at 150 [redacted] Hence, when taken in context, the message conveyed by Acambis' statements could not be literally false.

C. Plaintiffs Do Not Have a Legally Cognizable Delaware Claim

BN also fails to articulate an actionable claim under Delaware law.

First, there is no basis for invoking Delaware law. BN's opposition provides the first detailed explanation of its state law unfair trade allegations.[12] *See* D.I. 125, Pl. Opposition

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(. . . continued)

[redacted].

[12] That explanation makes apparent that the gravaman of its state claims is the same as its conversion claim – Acambis' receipt of MVA from the NIH. *See, e.g.*, D.I. 125, Pl. Opposition Br. at 35, ¶ (i) ("Anton Mayr and/or [BN] could sue … Baxter in Austria to enjoin Baxter from using the MVA 572 property"); *id.* at ¶ (ii) (asserting that it is unfair that Acambis got MVA "for free...from a known, unauthorized source"); *id.* at 37, ¶ (v) (asserting that Acambis was "well aware of the potential 'cloud' on its ability to commercialize MVA"); *id.* at 38, ¶ (viii) ("Acambis made unauthorized use of Bavarian Nordic's, and previously Anton Mayr's MVA").

Br. at 35-38. But there is no alleged injury in Delaware; BN is not incorporated in Delaware; none of Acambis' purported unfair acts occurred in Delaware; and BN had no relationship with Acambis in Delaware. *See ACCU Pers., Inc. v. Accustaff, Inc.*, 846 F. Supp. 1191, 1212 (D. Del. 1994) (applying "the 'most significant relationship' test" to determine applicable unfair trade law). Yet BN's Amended Complaint alleges unfair trade claims only under Delaware law. D.I. 85 at ¶ 65. As a result, BN's state law unfair trade claims, which only reference Delaware law, must be dismissed. *See Acker v. Transurgical, Inc.*, 2004 Del. Ch. LEXIS 49, at *14 (Del. Ch. April 22, 2004) ("If a plaintiff chooses to 'plead particulars, and they show he has no claim, then he is out of luck – he has pleaded himself out of court.'"), quoting *Jefferson v. Ambroz*, 90 F.3d 1291, 1296 (7th Cir. 1996).

Second, BN does not argue that its Delaware reverse passing off claims are any different than its Lanham Act claim. Nor does BN argue with this Court's previous finding that the *Dastar* precedent is equally applicable to state law claims. *See Monsanto Co.*, LEXIS 54515 at *13-15 (dismissing two state law claims for the same reason as the Lanham Act), citing *Toro Co. v. Textron, Inc.*, 499 F. Supp. 241, 249 n.17 (D. Del. 1980). Hence, BN's reverse passing off claims under state law are barred by *Dastar* because, as BN admits, Acambis and Baxter – not BN – manufacture the MVA3000 vaccine.

Third, BN does not dispute that Delaware law does not recognize false advertising claims based on "implied misrepresentations." D.I. 125, Pl. Opposition Br. at 32. Rather, BN asserts that its state law claims rely on Acambis' literally false statements – the very same statements upon which its Lanham Act claim is based. *See id.* As with its Lanham Act arguments, BN fails to cite a single literally false statement or a single piece of evidence from

which a juror could infer literal falsity. Therefore, BN's false advertising state law claims should be dismissed.

Fourth, in order to shoehorn many of its allegations into Delaware law, BN makes the novel argument that Acambis has engaged in a pattern of unfair conduct in violation of §2532(a)(12), which BN refers to as a "catch-all."[13] Yet BN fails to cite a single Delaware case justifying such an expansive definition of the statute.[14] The intent of §2532(a)(12) is not to remedy any conduct about which a plaintiff could possibly complain. Rather, the intent of the section is to "enable courts to prevent 'new kinds of deceptive trade practices.'" *Del. Solid Waste Auth. v. E. Shore Env., Inc.*, 2002 Del. Ch. LEXIS 34, at *21 (Del. Ch. March 28, 2002), quoting Uniform Deceptive Trade Practices Act § 2(a)(12), cmt. Here, BN does not assert any new kind of deceptive practice – rather, BN is asserting the very same claims that it is asserting under the other more specific subsections of §2532(a). For instance, BN's claims under §§2532(a)(1), (2), and (3) concerning Acambis' alleged reverse passing off of the MVA virus are the very same as its claims under §2532(a)(12). *Compare* D.I. 125, Pl. Opposition Br. at 32, *and* 33, *with id.* at 35-38 (iii), (v), (vi), (vii), (viii).

Further, in support of its "catch-all" argument, BN relies heavily on the Restatement (Third) of Unfair Competition, which includes a residual provision stating that "a person seeking relief under the residual rule … bears the burden of establishing that the method

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[13] Delaware's statute is broken down into twelve subsections; eleven of which are particular on their face and a twelfth subsection which is directed to "other conduct which similarly creates a likelihood of confusion." 6 Del. C. § 2532 (2006).

[14] The Supreme Court case cited by BN is a criminal case concerning the Live Poultry Code, which only discusses unfair competition generally, in dicta and makes no mention of the Deceptive Trade Practices Act. *See A.L.A. Schechter Poultry Corp. v. U.S.*, 295 U.S. 495, 839, 844 (1935). The other case cited by BN, *Delaware Express Shuttle, Inc. v. Older*, 2002 WL 31458243 (Del. Ch. 2002), is not an unfair trade case.

of competition employed by the actor is unfair." *See* RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 1 (1995). But BN fails to provide specific facts in support of its "catch-all" allegations. For instance, BN asserts that Acambis should have disclosed information to NIH concerning BN and/or Mayr's alleged Austrian rights, but there is not a single factual citation to support this allegation. *See* D.I. 125, Pl. Opposition Br. at 38 (vii), (viii). And in fact, BN's Austrian patent did not issue until December 28, 2005, *after* Acambis had submitted its responses to all three of the U.S. Government's RFPs. *See* Ex. 65, EP 1 335 987.

The Restatement also includes examples of business practices that fall within the Restatement's "catch-all," such as "interfer[ing] with the business of another by acts or threats of violence, ... instituting or threatening to institute groundless litigation," or defamation. RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 1 cmt. g (1995). None of the complaints in BN's litany of alleged unfair conduct fits into any of the categories listed in the Restatement, and BN makes no effort to line up the alleged conduct with any of the Restatement's provisions. *See* D.I. 125, Pl. Opposition Br. at 35-38. Further, Delaware has not adopted the Restatement wholesale. For instance, the Restatement recognizes that the misappropriation of trade secrets can be the basis for an unfair competition claim. *See id.* at § 1. Delaware, on the other hand, specifically does not recognize such a claim.[15] *See* 6 Del. C. § 2007 (2006) ("[T]his chapter displaces conflicting tort, restitutionary and other law of the State providing civil remedies for misappropriation of trade secret"). BN has failed to provide any *Delaware* precedent that would cover the purported unfair conduct claimed here.

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[15] In this regard, BN's claims concerning trade secrets, for example, its claim that "Dr. Moss provided Bavarian Nordic confidential business information to Acambis" are precluded. *See* D.I. 125, Pl. Opposition Br. at 36-37 (iv).

CONCLUSION

Based on the foregoing and the reasons set forth in defendants' opening brief in support of their motion to dismiss or, in the alternative, for summary judgment, judgment on plaintiffs' claims should be granted in favor of defendants pursuant to Fed. R. Civ. P. 12(c) and/or 56.

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CERTIFICATE OF SERVICE

I hereby certify that on January 19, 2007, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

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